



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	2775.02
True Name	Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	<p> Ingelvac Mycoflex - Agritech Enterprise Sdn. Bhd. Ingelvac Mycoflex - Boehringer Ingelheim (Thai) Ltd. Ingelvac Mycoflex - Boehringer Ingelheim Animal Health Australia Pty. Ltd. Ingelvac Mycoflex - Boehringer Ingelheim Animal Health Canada Inc. Ingelvac Mycoflex - Boehringer Ingelheim Animal Health Korea, Ltd. Ingelvac Mycoflex - Boehringer Ingelheim Animal Health Mexico Ingelvac Mycoflex - Boehringer Ingelheim Animal Health New Zealand Ltd Ingelvac Mycoflex - Boehringer Ingelheim Animal Health Philippines, Inc. Ingelvac Mycoflex - Boehringer Ingelheim Animal Health Portugal Ingelvac Mycoflex - Boehringer Ingelheim Animal Health South Africa (Pty) Ltd/ (Edms) Bpk Ingelvac Mycoflex - Boehringer Ingelheim Animal Health do Brasil Ltda Ingelvac Mycoflex - Boehringer Ingelheim India Pvt Ltd Ingelvac Mycoflex - Boehringer Ingelheim Ltda Ingelvac Mycoflex - Boehringer Ingelheim S.A. Ingelvac Mycoflex - Boehringer Ingelheim Serbia d.o.o. Beograd Ingelvac Mycoflex - Boehringer Ingelheim Vetmedica GmbH Ingelvac Mycoflex - Boehringer Ingelheim of Brazil Ingelvac Mycoflex - INSUVECA </p>
Date of Compilation Summary	December 02, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	<i>Mycoplasma Hyponeumoniae</i>
Study Purpose	Demonstration of the minimum efficacious dose
Product Administration	Administration of one dose intramuscularly
Study Animals	Pigs 3 weeks of age, divided into 20 vaccinates and 20 control pigs
Challenge Description	Challenged with <i>Mycoplasma hyopneumoniae</i> 28 days post vaccination
Interval observed after challenge	Pigs were observed for 27 days post-challenge for clinical signs of <i>Mycoplasma hyopneumoniae</i> infection and then tissues were examined for determination of lung lesions.
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 10, 2006

Study Type	Efficacy
Pertaining to	<i>Mycoplasma Hyopneumoniae</i>
Study Purpose	Demonstration of a 26 week Duration of Immunity
Product Administration	Administration of one dose intramuscularly
Study Animals	Pigs approximately 3 weeks of age, divided into 20 vaccinates and 20 controls
Challenge Description	Challenged with <i>Mycoplasma hyopneumoniae</i> 184 days post vaccination
Interval observed after challenge	Pigs were observed for 33 days post-challenge for clinical signs of <i>Mycoplasma hyopneumoniae</i> infection and then tissues were examined for lung lesions consistent with <i>Mycoplasma hyopneumoniae</i> infection.
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 7, 2006

Study Type	Safety																																				
Pertaining to	All																																				
Study Purpose	To demonstrate safety under field conditions																																				
Product Administration	Single intramuscular administration																																				
Study Animals	1355 pigs at 10 - 30 days of age, (≥ 200 pigs from each of three different geographical locations were vaccinated, and a similar number at each site were not vaccinated for comparison)																																				
Challenge Description	Not applicable																																				
Interval observed after challenge	Pigs were observed immediately following vaccination and then for 14 days following vaccination. No challenge was conducted.																																				
Results	<p>Observations of Vaccinated Pigs:</p> <table border="1"> <thead> <tr> <th>Clinical Observation ^a</th> <th>MO Site N=244</th> <th>NE Site N=229</th> <th>IN Site N=207</th> </tr> </thead> <tbody> <tr> <td>None ^b</td> <td>241</td> <td>210</td> <td>193</td> </tr> <tr> <td>Poor Condition ^c</td> <td>0</td> <td>15</td> <td>0</td> </tr> <tr> <td>Dead ^d</td> <td>3</td> <td>2</td> <td>3</td> </tr> <tr> <td>Scours</td> <td>0</td> <td>1</td> <td>10</td> </tr> <tr> <td>Lame</td> <td>0</td> <td>1</td> <td>0</td> </tr> <tr> <td>Swollen Joint(s)</td> <td>2</td> <td>0</td> <td>0</td> </tr> <tr> <td>Cough</td> <td>0</td> <td>0</td> <td>1</td> </tr> <tr> <td>Skin Abnormalities ^e</td> <td>0</td> <td>1</td> <td>1</td> </tr> </tbody> </table> <p>^a Pigs may have exhibited more than one clinical observation. ^b For an observation of “None” a pig had to be without clinical observations for the entire 14 days of the study. ^c Observations of “Poor Condition” included: thin starve, small thin, small, gaunt, gaunt weak, and thin. ^d Observation of “Dead” included: Dead, Died, and Euthanized. ^e Observation of “Skin Abnormalities” included: scabbed knees and skin spots</p>	Clinical Observation ^a	MO Site N=244	NE Site N=229	IN Site N=207	None ^b	241	210	193	Poor Condition ^c	0	15	0	Dead ^d	3	2	3	Scours	0	1	10	Lame	0	1	0	Swollen Joint(s)	2	0	0	Cough	0	0	1	Skin Abnormalities ^e	0	1	1
Clinical Observation ^a	MO Site N=244	NE Site N=229	IN Site N=207																																		
None ^b	241	210	193																																		
Poor Condition ^c	0	15	0																																		
Dead ^d	3	2	3																																		
Scours	0	1	10																																		
Lame	0	1	0																																		
Swollen Joint(s)	2	0	0																																		
Cough	0	0	1																																		
Skin Abnormalities ^e	0	1	1																																		

	Observations of Control Pigs:			
	Clinical Observation ^a	MO Site N=241	NE Site N=228	IN Site N=206
	None ^b	237	209	195
	Poor Condition ^c	0	13	0
	Dead ^d	4	2	1
	Scours	0	0	9
	Lame ^e	0	3	1
	Swollen Joint(s)	2	0	0
	Hernia ^f	0	2	0
	^a Pigs may have exhibited more than one clinical observation. ^b For an observation of “None” a pig had to be without clinical observations for the entire 14 days of the study. ^c Observations of “Poor Condition” included: thin, gaunt, gaunt/weak, and gaunt-purple ears. ^d Observation of “Dead” included: dead, died, and euthanized. ^e Observation of “Lame” included: lame, sore right front foot, and shoulder ^f Observation of “Hernia” included: hernia and surgery.			
USDA Approval Date	April 5, 2006			